

REMARKS

The withdrawn claims have been retained so that they can be returned to active consideration when patentability has been recognized. Nevertheless, withdrawn claims 24, 25, and 27 are effectively amended by the amendment to claim 1 and a corresponding text change has been made in withdrawn claim 28.

The Examiner's understanding of a constipation-dissolving amount as being based on the total amount of the composition is correct and claim 1 has been amended to explicitly so state. Accordingly, the rejection under the second paragraph of Section 112 can now be withdrawn.

The claims have been amended to make it clear that the composition is an injectable in accordance with page 5, line 22, and as illustrated in Example 4.

Claims 1 and 4 were rejected under 35 U.S.C. § 102 over Herslof. This rejection is respectfully traversed.

The Office Action correctly identifies the Herslof composition as a solid. This is further confirmed by page 3, lines 16-17, which refers to it as a "solid ... tablet or suppository composition". A solid preparation such as a tablet is not, of course, injectable, and therefore a rejection based on Section 102 is not tenable. Likewise, while a suppository may be insertable, it is not injectable. There is also nothing in this reference which would suggest to one skilled in the art to convert the composition disclosed into an injectable composition. The rejection should be withdrawn.

Claims 1-7 were rejected under 35 U.S.C. § 103 over Herslof and this rejection is respectfully traversed.

As noted above, Herslof relates to a solid tablet or suppository composition. There is nothing in the reference which would suggest to a person skilled in the art to convert the solid composition of the reference to an injectable. The injectable pharmaceutical composition of these rejected claims provides a treating composition which is efficient, has a rapid onset of action, which does not irritate the mucus of the bowel, and is convenient to administer, as noted on page 2, lines 7-10 of the specification. Accordingly, withdrawal of this rejection is respectfully solicited.

Claims 1-7, 9-12, 14, 15, and 17-19 were rejected under 35 U.S.C. § 103 over Herslof in view of Tomaru and Klaschik. This rejection is also respectfully traversed.

Herslof has been discussed above. Neither of the additional references is suggested in the Office Action to cure the basic deficiency in the primary reference, namely suggesting that the Herslof composition be somehow converted into an injectable.

Klaschik has been cited to show a rectally-administered tablet and the Office Action also acknowledges that the reference does not teach the specific components of a preferred embodiment of the instantly claimed invention. Moreover, one of the problems with enemas is, as stated on application page 2, lines 2-3, their administration is problematic because of leakage. The composition of the present invention does not suffer from this drawback.

Tomaru has been cited only for teaching that glycerol has been used for the treatment of constipation although it can induce Giant Migrating Contractions. To minimize such contractions, Tomaru suggests the administration of lidocaine. Further, as acknowledged in the Office Action, Tomaru does not teach the addition of an oily triglyceride or a polar lipid.

It is respectfully submitted that the contention that it would be obvious to adjust the amount of water to a range "for a use disclosed by Klaschik" is not valid since Klaschik's "use" involves administration of a solid tablet.

Claims 21-23 were rejected under 35 U.S.C. § 103 over Herslof in view of Klaschik and Stemmié.

Herslof and Klaschik have been discussed above and shown not to render the claimed invention obvious. Stemmié does not cure the basic deficiencies in this combination, and is not relevant to the claim feature for which it was cited.

Stemmié is stated in the Office Action to teach solid tablets and/or suppositories, a teaching also found in Herslof. Stemmié thus does not teach or suggest an injectable composition. The reference has also been cited to show a dynamic viscosity but to the extent it makes reference to such a viscosity, it is only to make a comparison between various batches of tablets to see if they are consistent with one another. It does not teach that the composition, i.e., the tablet, itself has (or should have) any particular dynamic viscosity. Note that Stemmié measures dynamic viscosity after first swelling the tablets in water with stirring. See, col. 4, lines 58-61. Thus, to the

extent that dynamic viscosity is disclosed in this reference, that disclosure is not relevant to the claims under consideration.

In light of the fact that all of the references cited do not teach or suggest an injectable composition and its use, it is readily apparent that those references, whether considered alone or in combination cannot negate the novelty and unobviousness of the instant claims. Withdrawal of all of the rejections and allowance of this case is, therefore, respectfully solicited.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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